Systematic assessment of clinical practice guidelines for the management of chronic obstructive pulmonary disease

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Abstract *Objective:* To systematically evaluate the quality of the development of guidelines for the management of chronic obstructive pulmonary disease (COPD). *Methodology*: MEDLINE and Excerpta Medica search for published guidelines, followed by independent evaluation by two reviewers, according to previously reported guideline development quality criteria, on a three-point scale. *Results:* Five national COPD guidelines and two international COPD guidelines were retrieved. Reviewers demonstrated good inter-observer agreement in assessing the 10 combined guideline development criteria for the seven guidelines [$\kappa = 0.66$]. Guidelines were only partly multi-disciplinary, with little or no consumer input, were up to 48 pages in length, and often lacked practical summaries or management flow charts which could have facilitated retrieval of key management recommendations. Almost all the papers were based upon a consensus approach, rather than evidence based, and methods of resolution of differences of opinion were not stated. Patient outcomes, ethical and medico-legal implications were not addressed and six of the guidelines were sponsored directly or indirectly by a single drug company. *Conclusions*: In spite of COPD guidelines being reported by major national bodies for over a decade now, most fail to meet important criteria for high-quality guideline development, and evaluation of clinical impact remains undetermined.

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Keywords lung diseases; obstructive; practice guidelines/standards; pulmonary disease (specialty)/ standards.

INTRODUCTION

Economic pressures from rising health-care costs, consumer expectations and corporatisation in health-care provision have increasingly directed the focus of health-care away from the patient to the health-care system (1), and consequently to the way health-care services are delivered. The promotion of clinical practice guidelines, based on the best available evidence, has resulted partly from the demonstration of considerable variations in clinical practice (2–7) which could not be explained by underlying differences in population risk factors or severity of disease. Variation in patient treatment, and hence costs, without improved health outcomes raises questions about the optimal use of limited resources. Evidence-based guidelines which link processes to outcomes provide a mechanism for improving efficiency and outcomes. However, despite the proliferation of guidelines, there is limited evidence of their uptake in clinical settings, and even less evidence of their impact on patient health outcomes (8). Reviews of guidelines of clinical topics other than chronic obstructive pulmonary disease (COPD) have demonstrated poor adherence to guideline methodological standards (7,9).

One barrier to guideline uptake is physician concern about the intent and validity of these documents (10). Further specific attributes reported in the literature that determine whether clinical practice guidelines are used in practice include the clarity and specificity of the guidelines (11), the strength of the evidence and its susceptibility to bias (12). Without effective methods to translate evidence into changes in clinical practice, potential benefits for patients will not be realised (13).

COPD management guidelines have been reported in the international biomedical literature since at least 1987, and have diverse contents (14). However, there is no evidence that these guidelines have been widely adopted in the health-care system, particularly in primary care, or

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impacted upon patient outcomes. Nor has there been evaluation of either the quality of guideline development or the strength of the evidence upon which COPD guidelines are based.

COPD is the fifth leading cause of mortality and burden of disease for the world, accounting for 4.2% of deaths worldwide (15). Given this burden of disease, and the associated health-care resources utilised, our aim was to systematically review the quality of the development of published guidelines for the inpatient management of COPD.

METHODS

Guidelines for the management of COPD were identified by a search of MEDLINE and Excerpta Medica from their commencement to 2001, using terms for COPD (lung diseases—obstructive, obstructive airways disease, emphysema, chronic airflow limitation, chronic obstructive lung disease) and guidelines (algorithms, critical pathways, guidelines, standards, optimal assessment, practice guidelines).

Selection criteria

- The guideline was written with clearly stated primary objectives relevant to COPD management.
- The latest guideline version available from an institution or society was used.
- Guidelines prepared for an exclusive and narrow audience were excluded, for example, for general practice or nursing only.

The quality of guidelines developed for the management of patients with COPD was assessed using the eight criteria of Ward (16); *applicability, validity (including assessment of strength of evidence), reproducibility, clinical flexibility, clarity, multi-disciplinary, documentation*, and *scheduled review*. These eight criteria are consistent with those used by Grilli *et al.* (9), Shaneyfelt *et al.* (7) and other guideline appraisal instruments (17). In view of increasing interest in the implications of guideline use, we added two further criteria, the demonstration of consideration of medico-legal implications (18–20), and of ethical considerations (21,22). Table 1 outlines the composition of each of the final 10 criteria.

A thoracic physician (PF) and an epidemiologist/scientist (AC) with expertise in clinical content and systematic reviews, independently evaluated the guidelines that met the selection criteria, using a scoring system of the extent to which each of the quality criteria were addressed; three for fully addressed, two for partially, and one for not at all. Extreme disagreements (score of three *vs*. one) between the raters were identified by a third party (KH), and further review occurred. A kappa statistic (23) was performed on the final ratings to assess inter-observer agreement.

RESULTS

Seven COPD guidelines met the selection criteria. Six guidelines originated from thoracic or respiratory societies (see Table 2) and the most recent, the Global initiative for chronic obstructive lung disease (GOLD), was initiated by a collaboration between the World Health Organisation (WHO) and the National Heart, Lung and Blood Institute (NHLBI). All included management recommendations for inpatients. Six included outpatient care recommendations (CTS (24), ERS (25), ATS (26), SAPS (27), TSANZ (28), GOLD (29)), four included emergency and general practice recommendations (BTS (30), ERS (25), SAPS (27), GOLD (29)), whilst two (ATS (26), TSANZ (28)) focussed particularly on hospital management (both inpatients and outpatients). The ATS (26), SAPS (27) and GOLD (29) guidelines also discussed surgical management issues.

Quality of guideline development

The findings of the independent reviewers, in relation to the 10 criteria specified in Table 1, are summarised below, with a graphical summary of the associated ratings in Fig. 1, and actual scored ratings of the two independent reviewers provided in Appendix 1.

Applicability

All of the guidelines listed in Table 2 described the patient population and included definitions of the disease COPD. A range of COPD sub-categories (BTS) and pathophysiological processes (CTS) were described. The published guidelines targeted an audience of principally general practitioners (SAPS, CTS) or physicians (ERS, TSANZ), or did not specify a target audience (ATS), or were aimed at a very broad audience (GOLD). Caregivers were also mentioned as being part of the target audience for one guideline (SAPS). There was a range of guideline objectives, including early detection, non-drug interventions and smoking intervention (TSANZ, GOLD), acute and ongoing care (BTS), and also epidemiology, risk factors, prognosis and staging (ATS, GOLD). Guidelines included management recommendations relevant to inpatient and outpatient care, with emphasis in the BTS and ERS guidelines upon emergency department and primary care, respectively. GOLD had the broadest range of objectives, including an international public health emphasis and disease prevention. This critique relates to one of six chapters, namely "Management of COPD" in which four components were identified: "Assess and Monitor Disease," "Reduce Risk Factors," "Manage Stable COPD" and "Manage Exacerbations."

Table I. Criteria for evaluation of guideline development quality; 1–8: from Ward and Grieco (16), in addition to two further criteria: 9 (18–20), and 10 (21,22).

Criteria	Items
1. *Applicability*	states health problem, describes patient population, and defines intervention, and relates to providers and patients
2. *Validity*	describes health outcomes, intervention costings, consensus methods, conflict with other guidelines, methods to identify and synthesise evidence, strength of evidence
3. *Reproducibility*	references sources of information used, and documents literature review processes by experts/outside panel
4. *Clinical flexibility*	describes how to handle clinical exceptions
5. *Clarity*	unambiguous use of headings, use of flow charts, and facilitation of easy retrieval of major points and recommendations
6. *Multi-disciplinary*	lists disciplines that developed the guidelines
7. *Documentation*	date of publication and an indication of the edition or version
8. *Schedule review*	date of review specified
9. *Medico-legal*	consideration of medico-legal implications
10. *Ethical*	statement of potential conflicts of interest, including sponsorship

Table 2. Guidelines for management of COPD retrieved according to selection criteria

Title	Society/ Association	Date
Guidelines for the assessment and management of COPD	CanadianThoracic Society (CTS)	Aug 1992
Guidelines for the management of COPD	Thoracic Society of Australia and New Zealand (TSANZ)	July 1995
Optimal assessment and management of COPD	European Respiratory Society (ERS)	August 1995
Standards for the diagnosis and care of patients with COPD	AmericanThoracic Society (ATS)	November 1995
BTS guidelines for the management of COPD	BritishThoracic Society (BTS)	December 1997
Guidelines for the management of COPD	South African Pulmonology Society (SAPS)	August 1998
GOLD	National Heart, Lung and Blood Institute (NHLBI)/World Health Organisation (WHO) (international)	April 2001

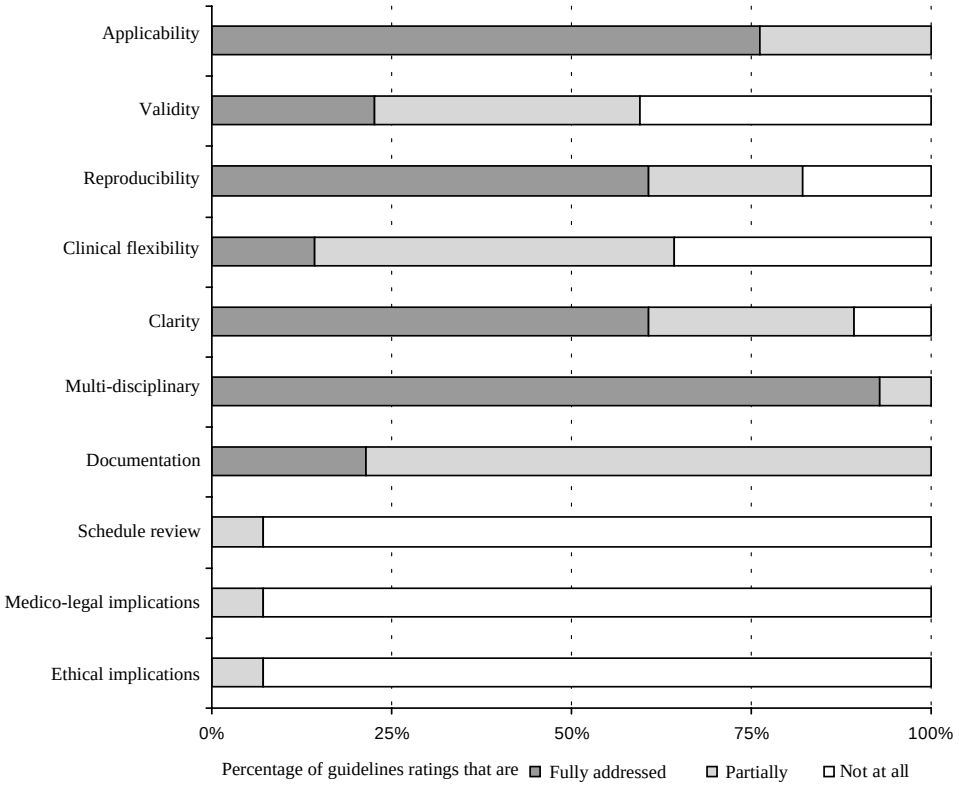

Fig. 1. The quality of COPD guideline development rated by two reviewers using criteria from Table I.

Validity

Assessment of items within the validity criteria, found that health outcomes were broadly discussed in the ERS, ATS and CTS guidelines, and specifically described in relation to each treatment for the BTS, TSANZ and GOLD guidelines. Costings of interventions were mentioned in several very specific instances in the TSANZ and ATS guidelines. There was little cost content in other guidelines. As GOLD was an international document, there was little scope for it to consider costs of interventions.

ERS and BTS guidelines described a structured approach to guideline development, with a series of working group meetings. One Thoracic Society sponsored a workshop (CTS), and a further Thoracic Society utilised a group of five Respiratory Physician authors (TSANZ), who held a simple consensus meeting to summarise discussions, although this was not stated in the published guidelines. The ATS, TSANZ, and CTS did not outline the methods used to identify evidence, synthesise evidence, or reach consensus. There was no indication of evaluation of the strength of evidence behind recommendations made, such as according to the categories proposed by Eccles *et al.* (31,32) for any of the guidelines, except for GOLD.

GOLD guidelines were developed over several years by consensus among international experts, namely "a distinguished group of professionals from the fields of respiratory medicine, epidemiology, socioeconomics, public health, and health education". In addition, there was widespread consultation with expert individuals and organisations from an extraordinary number of countries. It has not been made clear, however, as to the area of expertise of each individual consulted, although the methods used to develop the guideline were explicit in the document. Finally, the guideline was taken to the full membership of the American Thoracic Society and European Respiratory Society, then to the NHLBI and WHO before final publication. Methods for reaching consensus were stated, grading of levels of evidence were allocated by expert panel for critical statements and management recommendations. Conflict with other guidelines were not discussed.

Reproducibility

Guideline citation of the published literature ranged from no references (apart from recommended reading of five papers) for the SAPS guideline, to 265 references for the ATS guideline. Review of the literature for the CTS guideline was by the Canadian Thoracic Society Standards Committee, by a limited multi-disciplinary working group for the SAPS, and included discussion with "colleagues from North America" for the ERS

guideline. No statements were provided about search and review strategies in other guidelines. In GOLD, the sections relating to Management of COPD were accompanied by 314 references, provided by expert working parties.

Clinical flexibility

There was little or no discussion in any guidelines regarding management of clinical exceptions to broad recommendations, as would be expected in real-life situations, apart from ERS and GOLD. GOLD refers to patient variability in most sections, particularly in the Management chapter.

Clarity

The overall length and structure of the guidelines limited easy retrieval of the range of recommendations. Papers other than GOLD had an average length of 21 pages, ranging from nine (CTS, SAPS) up to 43 pages (ATS). The "Management of COPD" chapter of GOLD was 48 pages. Both the BTS and TSANZ guidelines provided summary overviews. GOLD and the ATS provided flow charts to guide treatment in specific circumstances. The BTS summary of guidelines, presented as a two-page document with clear diagrams, could provide clinicians with a clear working guide. ERS management algorithms were detailed, but legible and logical. The CTS guideline was presented in a narrative format without summaries or management algorithms, which is not ideal for rapid scanning for recommendations. All GOLD statements and recommendations had a level of evidence, and that evidence was clearly referenced. It also included boxes of key points as summaries, with levels of evidence clearly presented.

Multi-disciplinary

All of the guidelines provided a list of participants who developed the guidelines, but none specifically included purchasers, patients or consumers. BTS processes included consultation with general practitioners, nurses and lay groups. The SAPS guideline included input from medical schools, physiotherapists, pharmacologists, and anaesthetists, but no general practitioners, though it was stated to be directed to general practice. The ATS guideline had input from one registered nurse and a radiotherapist. TSANZ and CTS guidelines input was from respiratory physicians, and did not include consideration of advantages of multi-disciplinary input (12). GOLD guidelines were reviewed by a long list of participants and organisations, with expert panel input from fields of respiratory medicine, epidemiology, socioeconomics, public health and health education. Specific areas of clinical expertise (general practice, nursing, allied health) were not explicit.

Documentation/ schedule review

The ATS guideline was a complete revision of 1987 guidelines for ATS. Other documents represented first time publications, and schedules for review were not stated.

Medico-legal implications

No guidelines discussed the medico-legal implications of non-adherence to practice recommendations.

Ethical implications

A single drug company provided direct sponsorship for the SAPS, BTS, ERS, ATS, and CTS guidelines, and the TSANZ guidelines were indirectly supported from the same source. For development of the GOLD guidelines, sources of educational grants were identified, including 16 pharmaceutical and chemical companies. Six of the guideline groups acknowledged the financial support received but none included statements about potential conflicts of interest. Apart from GOLD, guidelines included specific unreferenced recommendations comparing use of medications between conditions, such as "anticholinergic agents are more effective in COPD than in asthma" (25). There are also unreferenced comparisons between medications, such as "once symptoms become continuous, ipatropium bromide should be given, as it provides benefits over β_2 agonists by producing fewer side effects, more prolonged action and less tachyphylaxis" (33).

Inter-reviewer agreement

The two independent reviewers were in complete disagreement (one vs. three) for only seven out of a total of 133 items, and were asked to score those items again, blinded to the assessment of the other reviewer. Following this, the final inter-observer agreement, in relation to the 10 guideline development criteria for each of the six guidelines, was good. [$\kappa = 0.66$] (23). [Final reviewer scores—see Appendix 1.]

DISCUSSION

There has been increasing interest in clinical practice guidelines and evidence-based medicine in recent years. We therefore evaluated the quality of development of guidelines for the major condition of COPD. We found that much of the development of published COPD guidelines has not followed methodological standards, a finding consistent with reports of guidelines relevant to

other clinical topics (7,9). There was inconsistency within and between the seven published COPD guidelines with respect to development quality criteria; and there had been little progress in development quality from 1987 to 1998. The GOLD guideline (2001) was the most comprehensively developed to date, with recommendations clearly linked to the evidence, including ratings of the strength of the evidence. Six guidelines were sponsored directly or indirectly by a single drug company, and the seventh (GOLD) was sponsored by multiple companies, although there was almost no discussion of ethical implications or statements of potential conflict of interest.

From this review, there are important unmet needs displayed in the published COPD guidelines. Validity of the processes of development of the published guidelines was limited. There has been an emphasis upon medical model consensus agreement rather than a multi-disciplinary approach in some guidelines (12,34). A structured approach for retrieval, appraisal, rating and presentation of the available evidence is important (34–37), yet lacking. Little has been done to ensure the practical retrieval of key recommendations in real-life clinical settings. These limitations and a lack of clinician confidence in consensus- and opinion-based statements (38) may impede uptake of guidelines by clinicians. Indeed, there has also been no evaluation of the impact of published COPD guidelines upon such clinical uptake, or upon patient outcomes.

Consumer participation was not reported for any of the reviewed guidelines, apart from input of a lay group for the BTS guideline. It is important that guidelines include consumers in development and implementation (39,40) so that guideline priorities and embedded values correspond to those of the targeted patient group (41,42).

The inculpatory use of guidelines by plaintiff lawyers may be a concern for clinicians. Under United Kingdom common law, the standard of minimal acceptable care is based on responsible practice and discretion and not on guidelines (20) while in the U.S., guidelines have already featured in 6.6% of recent medico-legal cases (19,43). As this issue is likely to become increasingly important, consideration of medico-legal and ethical considerations were included as criteria of development quality in our review. Little consideration has been given to this area in published COPD guidelines.

Our review has several limitations. The interpretation of criteria such as clarity may be somewhat subjective. However, unlike the review by Shaneyfelt *et al.* (7) we chose not to use a composite score to rate guideline quality, but instead chose to evaluate each criterion separately and independently. We also used a three-point rating scale (as opposed to Shaneyfelt's Yes/No scale) to rate each guideline as this enables a more detailed assessment of guideline quality, and we have demonstrated a good level of agreement in ratings between two independent observers.

A further limitation of our review is that the reported process of guideline development may not fully reflect all that was performed. We made no attempt to contact the lead authors of any of the guidelines for clarification of the development process. Documentation of guideline development is critical to allow readers to discern guideline development quality, and should be addressed in a transparent manner.

In our review, we did not include reports related specifically to evaluation of interventions based upon improving discharge from hospital, such as by use of a comprehensive patient work up, and discharge criteria checklists (44–46). These specifically focussed reports have demonstrated positive clinical outcomes, as well as examples of methodologies for the evaluation of guideline impact.

The development of multi-disciplinary, evidence-based guidelines, with attention to the needs of clinician and patient stakeholders, requires substantial effort. The British Thoracic Society is moving to base its next COPD guidelines on the highly structured evidence evaluations provided by Cochrane reviews, as is the Thoracic Society of Australia and New Zealand. For further progress to occur, there is a need for collaborative sharing of the work effort, and ongoing improvement through evaluation and feedback. The GOLD Initiative undertook an extensive review of evidence and wide multi-disciplinary international consultation over several years prior to release of the GOLD guidelines and its database (supplemented by the Cochrane database), has formed the basis of the new TSANZ guidelines. As COPD is a condition of major morbidity and mortality, it appears reasonable that independent (or health service funded) sources of support be obtained, particularly given the cost and ethical implications of many guideline recommendations.

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Appendix 1 The quality of COPD guideline development, by Table I criteria: scored as 3: fully addressed, 2: partially or 1: not at all, by two independent reviewers [AC, PF].

Criteria	ATS	TSANZ	CTS	SAPS	BTS	ERS	GOLD
Applicability							
States health problem	3, 3	3, 3	2, 3	2, 3	3, 3	3, 3	3, 3
Describes patient population	2, 3	2, 3	2, 3	2, 3	3, 3	3, 3	3, 3
Defines intervention	3, 3	3, 2	2, 2	3, 2	3, 3	3, 3	3, 3
Validity							
Health outcomes listed	3, 3	2, 3	2, 2	2, 2	3, 3	3, 3	3, 3
Costings of intervention	2, 2	1, 2	1, 1	1, 1	1, 1	1, 1	2, 2
Method for reaching consensus	1, 1	1, 1	2, 2	3, 3	3, 3	2, 3	2, 3
Conflict with other guidelines	1, 1	1, 1	1, 1	1, 1	1, 2	2, 2	2, 1
Method used to identify evidence	1, 1	1, 1	2, 1	2, 2	3, 2	2, 1	2, 2
Method used to synthesise evidence	1, 1	1, 1	2, 1	2, 3	2, 2	3, 3	2, 2
Reproducibility							
References information sources	3, 3	2, 3	3, 2	2, 1	3, 3	3, 3	3, 3
Document reviewed by experts/outside panel	2, 1	1, 1	3, 3	3, 3	2, 1	3, 2	3, 3
Clinical flexibility							
Information about exceptions	2, 1	2, 1	1, 2	1, 1	2, 2	2, 3	2, 3
Clarity							
Clear headings, flow charts, indices	3, 3	1, 2	1, 2	3, 3	3, 2	3, 3	3, 3
Major recommendations retrieval	3, 2	2, 3	2, 2	2, 1	3, 3	3, 3	3, 3
Multi-disciplinary							
Lists guideline development participants	3, 3	3, 3	3, 3	3, 3	3, 3	2, 3	3, 3
Documentation							
Publication Date, Edition stated	2, 2	2, 2	2, 2	2, 2	2, 2	3, 2	3, 3
Schedule review							
Date of review specified	2, 1	1, 1	1, 1	1, 1	1, 1	1, 1	1, 1
Medico-legal implications	1, 2	1, 1	1, 1	1, 1	1, 1	1, 1	1, 1
Ethical implications	1, 1	1, 1	1, 1	1, 1	1, 1	1, 1	2, 1